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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,857	07/18/2003	James C. Wang	61816-00010	2932

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EXAMINER	
BUTLER, PATRICK NEAL	

ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,857	WANG, JAMES C.	
	Examiner	Art Unit	
	Patrick Butler	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51,52 and 63-78* is/are pending in the application.

4a) Of the above claim(s) *75 and 78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51,52,63-74,76 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18 July 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 75 and 78 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 June 2005.

Claim language in claims 69 and 70 pertaining to the product being selected from "an electrical cable, hose pipe, compression fitting, heat shrinkable tube, artificial turf, fabric, or shoe lace" is not considered and is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 June 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 65 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 claims means for mixing and means for discharging. However, the specification does not disclose the structure, material, or acts for performing the recited function. See MPEP §2181:

> If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. 112, second paragraph. Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002) (Court

> interpreted the language of the "third monitoring means for monitoring the ECG signal...for activating ..." to require the same means to perform both functions and the only entity referenced in the specification that could possibly perform both functions is the physician. The court held that excluding the physician, no structure accomplishes the claimed dual functions. Because no structure disclosed in the embodiments of the invention actually performs the claimed dual functions, the specification lacks corresponding structure as required by 35 U.S.C. 112, sixth paragraph, and fails to comply with 35 U.S.C. 112, second paragraph.).

In view of the lack of specification support, for purposes of examination, "means for" language is given is broadest reasonable meaning.

Claim 70 as amended teaches "rerouting part of the material through a rerouting channel... to form... a product." For purposes of examination, the claim is taken to mean that some material does reroute through a rerouting channel, it is not made into a product. The product is made from the material not rerouted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent Publication No. JP 63 158 382 (J '382).

Reference J '382 teaches a method of forming a product by using a tip-and-die assembly (See Figure 2, generally Ref. No. 11) with a first injector (screw and piston of Ref. No. 20) and a second injector (screw and piston Ref. No. 22), wherein the tip-and-die is a pressure-due assembly (pressure supplied by pipe of Ref. No. 24). The first non-molten material (Ref. No. 21) and second non-molten material (Ref. No. 23) are

introduced into the injectors and melted inside the respective injectors. The first molten material and second molten material are injected out (see Ref. No. 14 and 16) of the first and second (Ref. No. 16) injector around the tip. The first and second molten material is discharged from the tip through the die (at Ref. No. 12).

With respect to Claim 65, the presentation of the claim indicates that a method is claimed. However, no steps in the method are explicitly recited. For purposes of examination, the claim is interpreted to recite the structure as described in the claim as well as the steps of mixing and discharging, rather than merely the structural limitations of "means for."

Reference J '382's meeting of two molten materials at the die (See J '382, Fig. 2, generally Ref. No. 12) would inherently allow some degree of mixing the materials. Given that the material is leaving through the tip, it is inherent that there is some means present for discharging the mixed material from the tip through the die.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. JP 63 158 382 (J '382) as applied to claim 51 above, and further in view of Ulmachneider et al. (US Patent No. 3,833,329).

With respect to Claim 52, Reference J '382 teaches a method of forming a product using injectors as previously described.

Reference J '382 does not teach a reciprocating-screw type injector with reciprocating screws.

Nonetheless, reciprocating-screw type injectors are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a reciprocating-screw type injector in the method of J '382 because it would allow for transitioning quickly between short production runs.

Moreover, Ulmachneider teaches melting plastic to be shaped. Ulmachneider teaches injection molded and teaches preferably utilizing reciprocating screws and injection chambers. This combined unit is a reciprocating screw injector (See col. 15, lines 19-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Ulmachneider's reciprocating-screw type injector in the method of J '382 because it would provide an intermittent supply of molten thermoplastic.

Claims 63, 66, 67, 69-71, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. JP 63 158 382 (J '382), in view of Wang (US Patent No. 5,622,665).

With respect to Claims 63 and 66, Reference J '382 teaches a method of forming a product by using a tip-and-die assembly (See Figure 2, generally Ref. No. 11) with a first injector (screw and piston of Ref. No. 20) and a second injector (screw and piston

Ref. No. 22), wherein the tip-and-die is a pressure-due assembly (pressure supplied by pipe of Ref. No. 24). The first non-molten material (Ref. No. 21) and second non-molten material (Ref. No. 23) are introduced into the injectors and melted inside the respective injectors. The first molten material and second molten material are injected out (see Ref. No. 14 and 16) of the first and second (Ref. No. 16) injector around the tip. The first and second molten materials are discharged from the tip through the die (at Ref. No. 12).

Reference J '382 does not teach a method of providing a diverting channel, wherein the diverting channel selectively diverts material flowing between the tip and the die.

Wang teaches a method of making forming a product using a tip-and-die assembly. Wang teaches utilizing modulator to bleed (divert) resin "A" (a selected material). Wang teaches that a modulator (diverting channel) bleeds (diverts) from the head (in the housing) (See Fig. 2, Ref. No. 20 and Col. 7, lines 46- Col. 8, line 11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Wang's diverting channel and method of rerouting with Reference J '382's method of making a product in order to relieve residual pressure (see Wang Col. 7, lines 46- Col. 8, line 11) and to actuate and regulate the flow of resins from the head, such as while extruding, similarly to how the other regulators (diverting channels) are used.

Additionally, with respect to Claim 63, Wang does not disclose expressly the exact location of the diverting channel within the housing as between the tip and the die.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to locate Wang's diverting channel between the tip and the die because Applicant has not disclosed that the exact location of the diverting channel within the housing as between the tip and the die provides an advantage, is used for a particular purpose, or solves a stated problem. One of the ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Wang because Wang's diverting channel within the head/housing would have been located for optimized utility within the head.

Therefore, it would have been an obvious matter of design choice to modify Wang to obtain the invention as specified in claim 63.

With respect to Claim 67, Wang teaches using different materials, such as nylon and ethylene vinyl acetate, as the two materials (see Col. 15, lines 19-37).

With respect to Claim 69, J '382 teaches a product forming method with a tip-and-die with a tip, die, and two injectors, utilizing the injectors to inject their respective materials around the tip and discharging the mixed material as previously described. The material would have a degree of mixing due to being in contact and in a molten state as previously described.

Reference J '382 does not appear to explicitly teach medical product end uses.

Wang teaches that the tubing product is useful for a medical product (See Wang abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Wang's end use of medical product with Reference J

'382 because of reasons previously described and because Wang teaches additional end uses/applications and the respective detailed requirements of manufacturing pertaining to medical use (See Wang Col. 1-3).

With respect to Claim 70, Wang and J '382 teach a product forming method with a tip-and-die with a tip, die, and two injectors, utilizing the injectors to inject their respective materials around the tip and rerouting part of the flowable material as previously described.

Reference J '382 does not appear to explicitly teach medical product end uses.

Wang teaches that the tubing product is useful for a medical product (See Wang abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Wang's diverting channel and method of rerouting and end use of medical product with Reference J '382's method of making a product in order to relieve residual pressure (see Wang Col. 7, lines 46- Col. 8, line 11), to actuate and regulate the flow of resins from the head, such as while extruding, similarly to how the other regulators (diverting channels) are used, and because Wang teaches additional end uses/applications and the respective detailed requirements of manufacturing pertaining to medical use (See Wang Col. 1-3).

With respect to Claim 71, Wang teaches using different materials, such as nylon and ethylene vinyl acetate, as the two materials (see Col. 15, lines 19-37).

With respect to Claims 76 and 77, Wang teaches taking the catheter tube made by the process (first product) and assembling it into a catheter (second product, medical product) (See Wang, Fig. 14, and Col. 14, lines 1-22).

Claims 63 is further rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. JP 63 158 382 (J '382), in view of Wang (US Patent No. 5,622,665) and Stewart (US Patent No. 3,443,984).

With respect to Claim 63, Reference J '382 and Wang teach a method of making a product using a tip-and-die and discharging a material through the die as previously described.

Stewart teaches a process of making a product (coated tube) (See abstract) with a tip (See Fig. 2, generally location of Ref. No. 30) and a die (Ref. No. 12). When the diverting channel is opened up, its source begins at the area immediately between the tip and die, thus diverting material flowing between the tip and the die.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Stewart's diverting channel location with the method of making a product as taught by Reference J '382 and Wang because it provides guidance on where to locate a diverting channel within the housing for diverting purposes as taught by Wang and to allow the system to be flushed with solvent to clear the system after use (see Col. 3, lines 48-63).

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. JP 63 158 382 (J '382), in view of Wang (US Patent

No. 5,622,665) and Stewart (US Patent No. 3,443,984) as applied to Claim 63 above, and further in view of Zdrahala (US Patent No. 5,156,785).

Reference J '382, Wang, and Stewart teach a method of making a product using a tip-and-die and discharging a material through the die as previously described.

Reference J '382, Wang, and Stewart do not teach one of the housing or top revolving relatively around the other.

Zdrahala teaches extruding catheters (See abstract) through a die. Zdrahala teaches that rotating the outer and inner walls, or the orifice and mandrel (housing or tip).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Zdrahala's rotating the housing or tip with Reference J '382, Wang, and Stewart's method of making a product with a tip-and-die because it provides a catheter section of relatively low rotational stiffness and relatively high longitudinal stiffness, with such a physical property being desired to facilitate advancement through small arteries or veins (see col. 2, lines 37-53).

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. JP 63 158 382 (J '382), in view of Wang (US Patent No. 5,622,665) and as applied to Claim 66 as previously described, and further in view of Ezaki (US Patent No. 4,659,531).

With respect to Claim 68, Reference J '382 in view of Wang teaches a method of making a product as previously described.

Wang teaches using a hard and soft material as the two materials being injected (see Col. 15, lines 19-37).

Reference J '382 and Wang do not teach using first and second materials being different grades of the same material.

Ezaki teaches a method of manufacturing a product using a tip-and-die assembly (See Fig. 7). Like Wang, Ezaki also teaches using a hard and soft material as the two materials being injected. Ezaki teaches using HDPE for the hard material and LDPE as the soft resin material. As these are both polyethylene, their distinction is the grade HD or LD (See Ezaki Col. 7, Lines 3-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Exaki's HDPE and LDPE as the materials for use in the method of making a product as taught by Reference J '382 and Wang because it provides materials that have an affinity such that they can stick together strongly at the interface thereby allowing formation of an integrated structure or gradual change in the composition. Moreover, an adhesive agent's use is precluded (See Ezaki Col. 7, Lines 3-20).

Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. JP 63 158 382 (J '382), in view of Wang (US Patent No. 5,622,665) and as applied to Claim 71 as previously described, and further in view of Ezaki (US Patent No. 4,659,531).

With respect to Claim 72, Reference J '382 in view of Wang teaches a method of making a product as applied to Claim 71 as previously described.

Wang teaches using a hard and soft material as the two materials being injected (see Col. 15, lines 19-37).

Reference J '382 and Wang do not teach using first and second materials being different grades of the same material.

Ezaki teaches a method of manufacturing a product using a tip-and-die assembly (See Fig. 7). Like Wang, Ezaki also teaches using a hard and soft material as the two materials being injected. Ezaki teaches using HDPE for the hard material and LDPE as the soft resin material. As these are both polyethylene, their distinction is the grade HD or LD (See Ezaki Col. 7, Lines 3-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Exaki's HDPE and LDPE as the materials for use in the method of making a product as taught by Reference J '382 and Wang because it provides materials that have an affinity such that they can stick together strongly at the interface thereby allowing formation of an integrated structure or gradual change in the composition. Moreover, an adhesive agent's use is precluded (See Ezaki Col. 7, Lines 3-20).

With respect to Claim 73 and 74, Wang teaches taking the catheter tube made by the process (first product) and assembling it into a catheter (second product, medical product)(See Wang, Fig. 14, and Col. 14, lines 1-22).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butler whose telephone number is 571-272-

8517. The examiner can normally be reached on Monday through Friday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PB

Patrick Butler
Examiner
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